Attachment 13.2 - Replaces original Section 15

K101547

Section 15 – Summary of Safety & Effectiveness Henke Sass Wolf GmbH 510(k) Submission

NOV 22 2010

Submitter:	Henke-Sass, Wolf GmbH Keltenstrasse 1 78532 Tuttlingen Germany
Manufacturing site:	ALMO Erzeugnisse Erwin Busch GmbH Grosse Allee 84 34454 Bad Arolsen Germany
Submission Correspondent / Contact Person:	Lyle Howard Corporation / Lynette Howard 106 East 5th Avenue Mount Dora, FL 32757

Premarket Notification information required by 21 CFR Part 807, subpart E is as follows:

1. GENERAL INFORMATION

Classification Name:	piston syringe
Common usual name:	piston syringe
Proprietary name:	sterile single use syringe (NORM-JECT®)

Establishment Registration Number (submitter):	8010418
Establishment Registration Number (manufacturing Site):	8010674

Classification: Class II, FMF, Panel: 80, Regulation Number: 21 CFR 880.5860

The purpose of this request is for marketing clearance of Henke-Sass, Wolf piston syringe because we have added a new purple-colored plunger for a new version of the syringe.

The piston syringes covered by this submission will have the same performance as already marketed devices. The only difference will be the coloring of the plunger in adding a master batch to the original material. The safety and effectiveness will be comparable to the predicate devices.

Indications for Use:

"The HSW NORM-JECT®- syringes are intended to be used to inject into, or withdraw fluids from the body. The 1 ml- syringe with a purple plunger, labeled with BOTOX® is exclusively produced for use with BOTOX® Cosmetic (onabotulinumtoxinA)."

SUBSTANTIAL EQUIVALENCE:

The Henke-Sass, Wolf piston syringe is substantially equivalent to the Henke-Sass, Wolf piston syringes under 510(k)# (K821537) and the B.Braun piston syringes under 510(k)# (K063280). (The manufacturing site of B.Braun is also ALMO, Establishment Registration Number: 8010674.)

SAFETY AND EFFECTIVENESS INFORMATION:

The Henke-Sass, Wolf piston syringe is well recognized as being safe and effective for the declared intended use. The Henke-Sass, Wolf piston syringe does have the identical operating principles and the same intended uses than the predicate devices such as Henke-Sass, Wolf piston syringes under 510(k) # K821537 and B.Braun piston syringes under 510(k) # (K063280) already in commercial distribution.

Testing conducted to assure safety and effectiveness includes but is not limited to:

- Biological evaluation of Medical Devices:

  ISO 10993-1:2009: Biological Evaluation for Medical Devices:

  ISO 10993-4:2002; Hemocompatibility

  ISO 10993-5:2009; Cytotoxicity

  ISO 10993-10:2002; Sensitization

  ISO 10993-10:2002; Irritation or Intracutaneous Reactivity

  ISO 10993-11:2006; Acute Systemic Toxicity

- ISO 7886-1: 1993; Sterile hypodermic syringes for single use
- ISO 594-1:1986; Conical fittings with 6% (Luer) taper for Syringes, Needles and other Medical Equipment, general requirements
- ISO 10993-7:2008: Biological Evaluation for Medical Devices; EtO- Residuals
- ISO 11135-1:2007: Sterilization Validation (EtO)

- ISO 11607-1:2006; Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2006; Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes

Summary of Performance Data

The performance data presented in this safety & effectiveness summary and the attachments presented with the 510(k) submission demonstrates that this device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Henke-Sass Wolf, GmbH
C/O Ms. Lynette Howard
Lyle Howard Corporation
106 East 5th Avenue
Mount Dora, Florida 32757

NOV 2 2 2010

Re: K101547
Trade/Device Name: Piston Syringe (Norm –Jet)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: November 3, 2010
Received: November 4, 2010

Dear Ms. Howard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

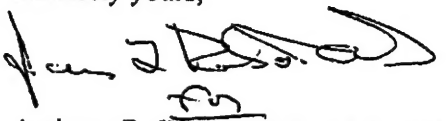
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 7.2 - Replaces Original Section 6

Section 6 – Indications for Use Statement - Revised

HSW- 510(k) for piston syringes

HENKE SASS WOLF

Indications for Use

NOV 22 2010

510(k) Number (if known): __K101547_____

Device Name: piston syringe

Indications for Use:

"The HSW NORM-JECT®- syringes are intended to be used to inject into, or withdraw fluids from the body. The 1 ml- syringe with a purple plunger, labeled with BOTOX® is exclusively produced for use with BOTOX® Cosmetic (onabotulinumtoxinA)."

Prescription use: X (Part 21 CFR 801 subpart D)

And /or

Over-the counter-use: --- (Part 21 CFR 801 subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101547